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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,660	08/22/2000	Jonathan Schneck	01107.00042	9271

7590 07/14/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/642,660	SCHNECK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28-32 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-31, 51-55, 59 and 60 is/are allowed.
- 6) ☒ Claim(s) 32 and 56-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

**Re: Schneck *et al***

**Priority Date: 28 March 1996**

1. The amendment filed 4/19/2004 is acknowledged and entered into the record. Accordingly, claims 1-27, 33-50 are canceled without prejudice or disclaimer.
2. Claims 28-32 and 51-60 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained –***

##### ***35 USC § 112, 1<sup>st</sup> paragraph (Written Description)***

4. The rejection of claims 32 and 56-58 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that the written description is intended to describe in detail that which is new or not conventional in the art and further argues that the novelty of the instant invention is the molecule complex and not the antigenic peptide. Applicant further argues that because antigenic peptides are well known in the prior art, the specification need not describe the antigenic peptides in order to find support. Applicant supports arguments by reference to Abbas *et al* and Smith *et al* and Akuzawa and Tsuchiya, of which are acknowledged. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The instantly claimed invention is drawn to a

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genus of antigenic peptides that is bound to a novel molecular complex.

Because the specification has not defined the broad class of antigenic peptides by any specific structure or motif nor with any specific functional activity, one of skill in the art cannot adequately envisage possession of the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In the instant case, the broad class of “antigenic” peptides claimed is well known in the art to be a highly divergent class of peptides, because just about any peptide sequence to some extent is considered “antigenic”. Because the specification has not provided a representative number of species in a highly divergent genus so that it can be used to encompass the broad scope of the peptides claimed, the written description for antigenic peptides has not been met.

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Applicant further argues that the examiner was in error for citing *Reagents of the University of California v. Lilly* because the case address written description for novel genetic material, and further states that none of the claims are drawn to genetic material. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The findings of *University of Rochester v. G.D. Searle & Co., Inc.*, F3.d, 2004 WL 260813 AT\*9 (Fed Cir. Feb 13, 2004) have since clarified that the findings of *Lilly* apply to written description for compounds other than cDNAs.

Therefore the written description rejection is maintained for the reasons of record.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Claims 28-31, 51-55, and 59-60 are free of the prior art.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

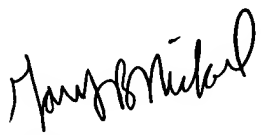
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
June 29, 2004

  
**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**